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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/057,561	01/29/2002	Johnson Chung	A8275	4657	
	7590 11/01/2002				
SUGHRUE MION, PLLC			EXAMINER		
2100 Pennsylvania Avenue, NW Washington, DC 20037-3213			LILLING, HERBERT J		
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			ART UNIT	PAPER NUMBER	
			1651	V	
			DATE MAILED: 11/01/2002	4	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	10/057,561	CHUNG ET AL.				
Office Action Summary	Examiner	Art Unit				
	HERBERT J LILLING	1651				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address P riod for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	36(a). In no event, however, may a reply b within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS f cause the application to become ABANDO	e timely filed days will be considered timely. rom the mailing date of this communication. DNED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on 23 C	October 2002 .					
2a) This action is FINAL . 2b) ⊠ Thi	This action is FINAL . 2b)⊠ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	,					
4) \boxtimes Claim(s) <u>1-4</u> is/are pending in the application.	☑ Claim(s) <u>1-4</u> is/are pending in the application.					
4a) Of the above claim(s) 2-4 is/are withdrawn f	4a) Of the above claim(s) <u>2-4</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.	Claim(s) is/are allowed.					
6) Claim(s) 1 is/are rejected.	☑ Claim(s) <u>1</u> is/are rejected.					
7) Claim(s) is/are objected to.	Claim(s) is/are objected to.					
8) Claim(s) 2-4 are subject to restriction and/or ele	ection requirement.					
···						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents	2. Certified copies of the priority documents have been received in Application No					
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)	,,					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Inform	nary (PTO-413) Paper No(s) nal Patent Application (PTO-152)				
S. Potent and Trademark Office						

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- 1. Receipt is acknowledged of the election response filed October 23, 2002.
- 2. Claims 1-4 remain pending in this application.
- Applicant has elected without traverse Group I, claim 1 drawn to claim1.
 Claims 2-4 have been withdrawn from consideration.
- 4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to the microorganism per se, see the following:

It is apparent that the strain is required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain . See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain and it does not appear to be a readily available material. Deposit of a strain

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would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;
- b) all restrictions imposed by the depositor on the availability to the public of the deposited material <u>will be irrevocably</u> removed upon the granting of a patent;
- c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function n the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

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A statement on the record with respect to the above (b) would be sufficient to withdrawn this rejection.

- B. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the lack of a suitable deposit of the microorganism as alleged to be the best mode.
- C. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific microorganism as disclosed if properly deposited, does not reasonably provide enablement for the exceptionally broad claimed language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the bacterium reads on a product of nature.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa et

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al U.S. 4,331,598 for ATCC 31565 or Hasegawa et al U.S. 4,450,234 for ATCC 15005.

Both of the deposited strains are considered to be within the scope of the broad claimed terminology since they have the same biological characteristics as claimed for the bacterium.

7. <u>No claim is allowed.</u>

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is** (703) 308-2034 and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL (703) 308-2034 Art Unit <u>1651</u> October 30, 2002

> Dr. Herbert J. Lilling Primary Examiner Group 1600 Art Unit 165

Group 1600 Art Unit 1651